



U.S. Pharmacopeia  
The Standard of Quality™

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## Dietary Supplements Manufacturers Gain New Tool to Help Ensure Quality Products

*Standards Compendium for Quality, Purity Helps Protect Consumers*

**Rockville, Md., July 7, 2009** — A first-of-its kind collection of standards designed to assist dietary supplements manufacturers in providing quality products to consumers is being released today by the U.S. Pharmacopeial (USP) Convention. The *USP Dietary Supplements Compendium (DSC)* will also help manufacturers in complying with Food and Drug Administration (FDA)-issued current Good Manufacturing Practices (cGMPs). Under these practices, manufacturers are responsible for the quality of the ingredients they use in manufacturing their finished dietary supplements.

The *DSC* is a comprehensive resource containing quality specifications for dietary supplements and their ingredients. These quality specifications include standards for identity, strength, purity and performance characteristics (e.g., dissolution, disintegration) of more than 500 dietary supplements and ingredients. In addition to these standards, the *DSC* includes general and regulatory information, guidance documents, appendices, and macro/microscopy, thin layer chromatography (TLC) and high performance liquid chromatography (HPLC) full-color images that greatly simplify the analysis of ingredients of botanical origin—making it a central repository of necessary information for dietary supplements manufacturers.

“With the release of this new *Dietary Supplements Compendium*, USP is seeking to partner with ingredient suppliers, dietary supplements manufacturers, contract laboratories, regulatory bodies and independent consultants to raise the quality of supplements and to fulfill the need for public standards in the dietary supplement community,” said James Griffiths, Ph.D., vice president of food, dietary supplement and excipient standards for USP. “With the current cGMPs from FDA stipulating that dietary supplements manufacturers determine the quality of ingredients they buy from suppliers by setting their own specifications, the *DSC* can significantly assist manufacturers by providing guidance on suitable specifications, including scientifically valid analytical methods and acceptance criteria. Consumers expect and deserve this kind of added protection.”

The *DSC* serves as a tool for manufactures in:

- Developing, manufacturing and testing new products;
- Qualifying raw materials;
- Preparing for international quality control and cGMP audits;
- Setting and validating standard operating procedures;
- Collecting in-process and batch-release tests; and
- Accurately packaging, labeling and storing products.

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The *DSC* draws its quality specifications from the *United States Pharmacopeia–National Formulary (USP–NF)* and the *Food Chemicals Codex (FCC)*, USP’s publications of standards for the identity, strength, purity and consistency of medicines and food ingredients, respectively. These specifications include items that may be considered dietary supplements or ingredients, including amino acids, vitamins, minerals, articles of botanical origin and their dosage forms. *USP–NF* is considered an official compendium under the Federal Food, Drug, and Cosmetic Act (FDCA), with the FDCA food misbranding provisions applying to any dietary supplement product represented as conforming to compendial specifications (and such products being deemed misbranded by FDA if they fail to so conform). USP has been setting quality standards for medicines for nearly 200 years.

For more information on the *DSC*, visit [www.usp.org/products/dietarysupplementscompendium/](http://www.usp.org/products/dietarysupplementscompendium/) or email [mediarelations@usp.org](mailto:mediarelations@usp.org).

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**USP—Advancing Public Health Since 1820**

The United States Pharmacopeial (USP) Convention is a scientific, nonprofit, standards-setting organization that advances public health through public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods. USP’s standards are recognized and used worldwide. For more information about USP visit <http://www.usp.org>. **FY1002**